marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product MONUROL™ (fosfomycin tromethamine). MONUROL™ is indicated only for the treatment of uncomplicated urinary tract infections (acute cystitis) in women due to susceptible strains of *Escherichia coli* and *Enterococcus faecalis*. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for MONUROL™ (U.S. Patent No. 4,863,908) from ZAMBON GROUP, S.p.A., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 1, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of MONUROL™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for MONUROL™ is 2,241 days. Of this time, 1,428 days occurred during the testing phase of the regulatory review period, while 813 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: November 2, 1990. FDA has verified the applicant's claim that the date that the investigational new drug application became effective was on November 2, 1990.

2. *The date the application was initially submitted with respect to the human drug product under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357)*: September 29, 1994. The applicant claims September 28, 1994, as the date the new drug application (NDA) for MONUROL™ (NDA 50–717) was initially submitted. However, FDA records indicate that NDA 50–717 was submitted on September 29, 1994.

3. *The date the application was approved*: December 19, 1996. FDA has verified the applicant's claim that NDA 50–717 was approved on December 19, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,525 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 16, 1997, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before January 14, 1998, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 8, 1997.

Allen B. Duncan,

Acting Associate Commissioner for Health Affairs.

[FR Doc. 97–18919 Filed 7–17–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96D–0137]

Medical Device Reporting, Guidance Document for Manufacturers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Medical Device Reporting (MDR) for Manufacturers.'' The guidance describes the new medical device reporting requirements for manufacturers, and it is intended for both domestic and foreign medical device manufacturers. The MDR regulations provide a mechanism for FDA to identify and monitor significant adverse events involving medical devices so that problems may be detected and corrected in a timely manner.

ADDRESSES: Submit written requests for single copies of the ''Medical Device Reporting (MDR) for Manufacturers'' guidance document to the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301–443–8818. Requestors will be sent a floppy diskette with a Microsoft Word document file containing the guidance document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Bryan H. Benesch, Center for Devices and Radiological Health, HFZ–220, 1350 Piccard Dr., Rockville, MD 20850, 301–443–7491, ext. 131.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 31, 1996 (61 FR 27361), FDA announced the availability of a draft guidance entitled ''Medical Device Reporting for Manufacturers.'' The guidance document contained information to help manufacturers comply with the new MDR regulations. The purpose of the guidance document was to: (1) Provide domestic and foreign manufacturers with a thorough description of the current MDR regulations; (2) give a clear

understanding of their reporting responsibilities and guidance to aid in the completion of the MDR forms; (3) give an overview of required written MDR procedures, records and files; and (4) supply information on sources for forms, instructions, and other MDR information.

Comments were requested and the guidance has been revised. FDA addressed the changes mandated by the Safe Medical Devices Act and the Medical Device Amendments of 1992.

''Medical Device Reporting (MDR) for Manufacturers'' represents the agency's current thinking on medical device reporting for manufacturers. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

II. Electronic Access

In order to receive the ''Medical Device Reporting (MDR) for Manufacturers'' guidance document via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt, press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number 987 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may do so by using the World Wide Web (WWW). The Center for Devices and Radiological Health (CDRH) maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a PC with access to the Web. The CDRH home page is updated on a regular basis and includes the ''Medical Device Reporting (MDR) for Manufacturers'' guidance document, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Medical Device Reporting for Manufacturers'' is available on the medical device reporting page at: http://www.fda.gov/cdrh/mdr.html.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

Dated: June 13, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–18918 Filed 7–17–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Submission for OMB Review; 30-Day Comment Period Proposed Information Collection: Evaluation of the IHS–Supported Alcohol and Substance Abuse Treatment Programs for American Indian/Alaska Native Women

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed information collection projects, the Indian Health Service (IHS) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection project was previously published in the **Federal Register** (62 FR 15191) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow 30 days for public comment to be submitted to OMB.

Proposed Collection.

Title: Evaluation of the IHS–Supported Alcohol and Substance Abuse Treatment Program for American Indian/Alaska Native (AI/AN) women. *Type of Information Collection Request:* New. *Need and Use of the Information Collection:* Section 703, ''Indian Women Treatment Programs'' of Public Law 102–573, the Indian Health Care Amendments of 1992, (the act) authorizes the IHS to develop and implement a comprehensive alcohol and alcohol and substance abuse (A/SA) program that specifically addresses the cultural, historical, social, and child care needs of AI/AN women. Section 801 of these Amendments requires a report on the progress made in meeting the objectives of the Act, a review of programs established or assisted pursuant to the Act, and an assessment of such programs. Support Services International, Inc, (SSI) an Indian-owned consulting firm, will develop the data collection instruments and conduct the study. The information collected will be used to assess and improve the effectiveness of the IHS-supported A/SA treatment program.

Data will be collected from a sample of AI/AN women who use the services provided by the IHS-supported A/SA treatment programs, and from a sample of treatment program staff. Findings from the study will be used to determine (1) What works, what does not work, and why; (2) what resources are required for successful A/SA treatment for AI/AN women; (3) what factors help or hinder women from maintaining sobriety; (4) how many women achieve success (3–, 6–, and 12-months after admission into A/SA treatment; (5) what are the characteristics, life conditions, and service needs of the women who use the treatment programs; (6) what are the common strengths and problems of the treatment programs, and what are recommendations for improvement. The study is expected to be completed in FY 1998. *Affected Public:* Individuals.

See Table 1 below for Types of Data Collection Instruments, Estimated Number of Respondents, Number of Responses per Respondent, Average Burden Hour per Response, and Total Annual Burden Hour.

TABLE 1

Data collection Instrument	Estimated no. of respondents	Responses per respondent	Average burden hour per response*	Total annual burden hrs
Project Director	24	1	0.75 hr (45 minutes)	18.0
Project Staff	216	1	0.50 hr (30 minutes)	108.0